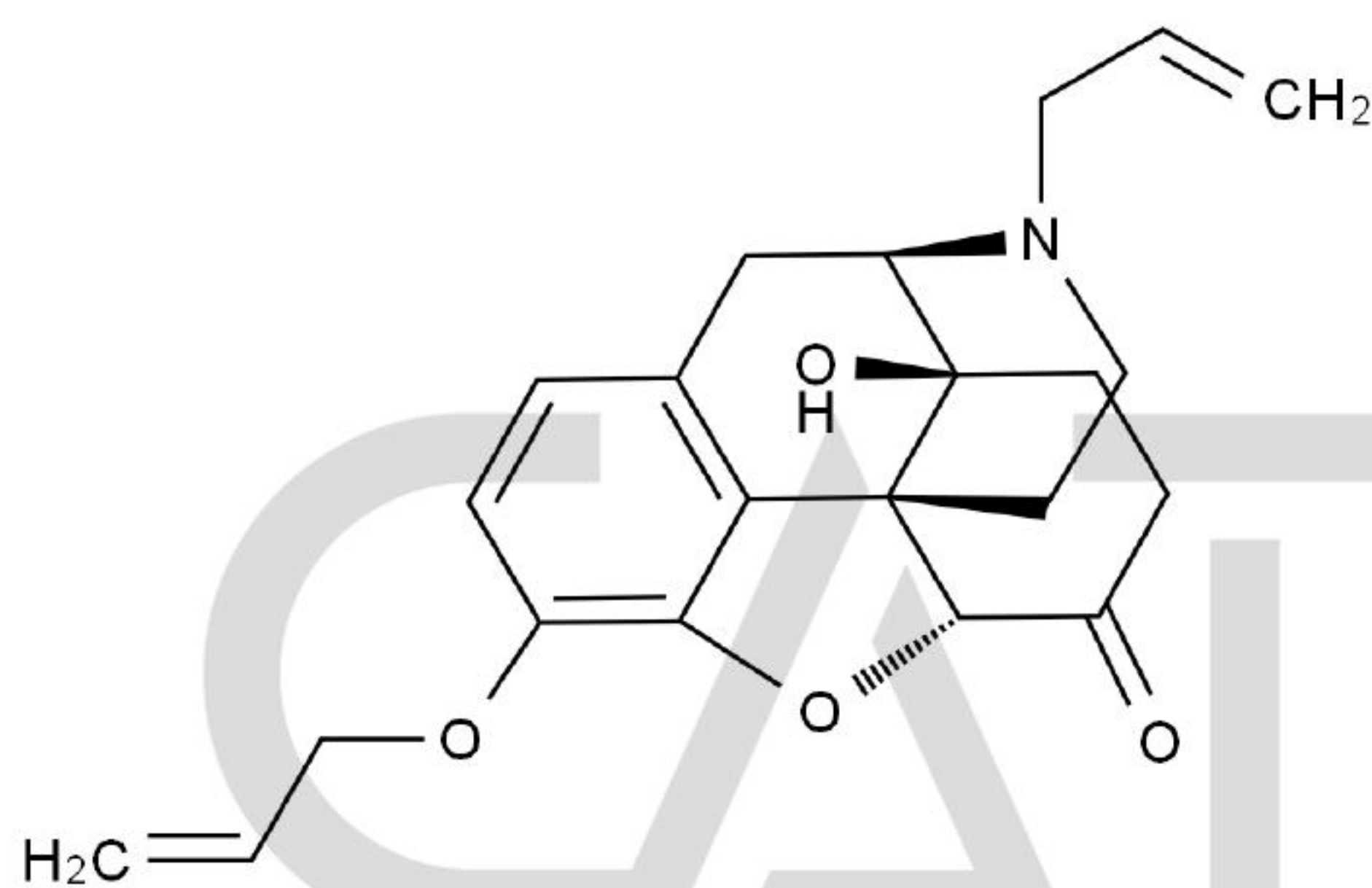


Certificate of Analysis

Reference Material & Standard

Product Name:	Naloxone Hydrochloride EP Impurity B	Catalogue Number:	C4X-14932
Synonyms:	4,5α-Epoxy-14-hydroxy-17-(prop-2-enyl)-3-(prop-2-enyloxy)morphinan-6-one	Lot Number:	0331-RG-0013
CAS Number:	1352085-46-1	Expiry Date:	Mar 05, 2030
Molecular Formula:	C ₂₂ H ₂₅ NO ₄	Storage:	2°C ~ 8°C Sealed
Molecular Weight:	367.44	Shipping Condition:	Shipping at Room Temperature
Solubility:	Soluble in acetonitrile and DMSO		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&IR&CNMR&HNMR	Confirmed
Purity	HPLC	99.858%
Residue on Ignition	TGA	0.7857%
Loss On Drying	TGA	0.0741%
Assay	qNMR	98.0%
Assay	Mass Balance	99.0%

Comment:

- The retest date of this product is Mar 05, 2029.
- The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

$$\text{Assay (\%)} = (100\% - \text{Residue on Ignition} - \text{Loss On Drying}) * \text{Purity HPLC (\%)} / 100\%$$
Residue on Ignition and Loss On Drying are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Koi

Reviewed by:

Alice

Approved by General Manager:

David

Date: Mar 06, 2026

Date: Mar 06, 2026

Date: Mar 06, 2026



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